



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

12/18/01

MEMORANDUM

SUBJECT: **Sodium Acifluorfen.** Revised Product and Residue Chemistry Chapters of the Reregistration Eligibility Decision (Chemical I.D. No. 114402; DP Barcodes D279845)

FROM: Felecia A. Fort, Chemist
Reregistration Branch 1
Health Effects Division (7509C)

THROUGH: Whang Phang, Ph.D., Branch Senior Scientist
Reregistration Branch 1
Health Effects Division (7509C)

TO: Christina Scheltema
Special Review and Reregistration Division (7508C)

Please find attached the product and residue chemistry chapters of the HED RED for **Sodium Acifluorfen**. These chapters were prepared by an HED contractor and have been revised to reflect current Agency policies. The product and residue chemistry databases are virtually complete. UV/visible absorption data (830.7050), and several labeling changes are the only outstanding requirements.

Changes have been made to these chapters to reflect comments submitted by the registrant during the Phase 3 evaluation of the Preliminary Human Health and Ecological Risk Assessment.

The following changes have been made to the Product and Residue Chemistry Chapters:

Product Chemistry

The regulatory history and bulk density have been corrected. The requirements for 830.1750 Certified Limits and 830.1800 Enforcement Analytical Method previously noted as being not applicable, are satisfied.

Residue chemistry

- The list of end use products has been changed to include Conclude Xact(EPA Reg. No. 7969-179) which was registered on March 29, 2000 and was erroneously omitted.
- HED no longer requires the registrant to replace the diazomethane used in the analytical method with an alternate methylating reagent.
- The requirement for radiovalidation of the analytical methods are waived based on the low residues found in metabolism and field trial studies.
- HED concurs that the limit of quantitation is likely less than 2.0 ppm for the acifluorfen amine and its methyl ester; however, the data does not support an LOQ of 0.05 ppm for the analyte. It is more likely somewhere between 0.05 and 0.1 ppm. No additional data will be required if method D9205 will not be used as an enforcement method.
- Since method D9205 will not be used as an enforcement method, an independent laboratory validation is no longer required.
- The typographical error on page 21 was corrected. The value was changed from 0.1 ppm to 0.01 ppm so that the statement reads "...¹⁴C - residues >**0.01** ppm accumulated in/on all rotational crop commodities of chard, turnip, sorghum, wheat, and radish planted 39, 103, 145, 313 and/or 370 days following application. [page 21].
- HED revised the rotational crop plant back interval requirement to 40 days for small grains and 100 days for other crops.

Attachment: 14 pp.

cc: F. Fort (HED), List B File, SF, RF

RDI: W. Phang:12/18/01;

7509C:CM2: 722:305-7478: 12/07/01

SODIUM ACIFLUORFEN

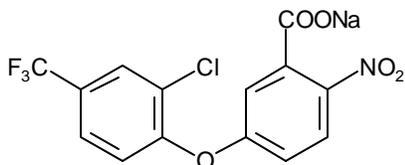
REREGISTRATION ELIGIBILITY DECISION:

PRODUCT CHEMISTRY CONSIDERATIONS

PC Code 114402; Case No. 2605

DESCRIPTION OF CHEMICAL

Sodium acifluorfen [sodium 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate] is a selective pre- and postemergence herbicide registered for control of annual broad-leaf weeds and some grasses in rice, peanuts, and soybeans.



Empirical Formula:	C ₁₄ H ₆ ClF ₃ NNaO ₅
Molecular Weight:	383.6
CAS Registry No.:	62476-59-9
PC Code:	114402

IDENTIFICATION OF ACTIVE INGREDIENT

Sodium acifluorfen TGAI (-78% pure) is a light yellow powder with a melting point of 274-279 C (with decomposition), bulk density of 25.11 lb/ft³ (free fall) and 32.08 lb/ft³ (packed), octanol/water partition coefficient (P_{ow}) of 1.55 at pH 7, and vapor pressure of <1.33 x 10⁻⁵ Pa at 25 C. Sodium acifluorfen is soluble in water (62.07 g/100 g), and most organic solvents (64.15 g/100 mL in methanol, 5.37 g/100 mL in octanol), and is practically insoluble (<5.0 x 10⁻⁵ g/100 mL) in hexane at 25 C.

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 3/6/00 identified a single sodium acifluorfen manufacturing-use product (MP) registered under PC Code 114402: the BASF Corporation 39.6% formulation intermediate (FI; EPA Reg. No. 7969-87). Because sodium acifluorfen is a list B chemical, only the BASF TGAI is subject to a reregistration eligibility decision.

REGULATORY BACKGROUND

The Sodium Acifluorfen Phase 4 Review dated 2/14/91 by S. Funk determined that data submitted for stability and solubility (OPPTS 830.6313 and 7840) were acceptable for Phase 5 review, and indicated that the registrant had committed to provide new studies for the remaining product chemistry data requirements. BASF has since submitted all new product chemistry data in support of the reregistration of sodium acifluorfen.

Rohm and Haas Company was the first registrant of sodium acifluorfen. This first registration was granted for the Rohm and Haas product Blazer herbicide in 1980. In 1987, BASF purchased the registration and data that supported that product. BASF contracted for the toll manufacture of the active ingredient at the Rohm and Haas facility in Bayport, Texas. Rohm and Haas has continued to toll manufacture the active ingredient for BASF under the Rohm and Haas process since the purchase and continues to produce sodium acifluorfen using that original manufacturing process. Under the requirements of PR Notice 87-7, BASF registered the sodium acifluorfen manufacturing use product that is produced at the Rohm and Haas facility so that product could be moved from Bayport, Texas to various BASF formulating facilities.

In 1984, Rhone-Poulenc registered its own sodium acifluorfen product, Tackle. Rhone-Poulenc used a slightly different manufacturing process; material was produced in a separate facility in Tennessee. In 1992, Rhone-Poulenc relinquished its sodium acifluorfen business and sold its database for sodium acifluorfen to BASF. Rhone-Poulenc no longer maintains any registrations for Tackle.

The product chemistry data base that BASF has submitted to EPA under the requirements of FIFRA '88, and that EPA has found to be acceptable, has been generated for material produced in the Rohm and Haas production facility.

The current status of the product chemistry data requirements for the BASF sodium acifluorfen TGAI is presented in the attached data summary table. Refer to this table for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

All pertinent product chemistry data requirements are satisfied for the BASF sodium acifluorfen TGAI except that additional data are required pertaining to UV/visible absorption (OPPTS 830.7050). Provided that the registrant submits the data required in the attached data summary table for the sodium acifluorfen TGAI, and either certifies that the suppliers of beginning materials and the manufacturing process for the sodium acifluorfen TGAI have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, HED has no objections to the reregistration of sodium acifluorfen with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s): 8172
DP Barcode(s):D165551
Subject: Sodium Acifluorfen Unregistered Technical (ID# 114402-007969). Phase 5 - Reregistration. BASF Corporation Response to the Sodium Acifluorfen Phase 4 Data Requirement: Product Chemistry.
From: F. Toghrol
To: L. DeLuise/T. Luminello
Dated: 5/5/92
MRID(s): 41650302, 41784601, 41891201-41891206, and 41891209

CBRS No(s): 8168
DP Barcode(s):D165645
Subject: Sodium Acifluorfen: Phase V Reregistration Review: BASF's Response to Product Chemistry Requirements.
From: W. Smith
To: C. Rice/T. Luminello
Dated: 9/29/92
MRID(s): 41731901

PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

References (cited):

41650302 Hambrick, A. (1990) Acifluorfen-sodium--Determination of Solubility Lab Project Number: 4053-90-0183-AS. Unpublished study prepared by Ricerca, Inc. y Ricerca, Inc. 23 p. prepared by Ricerca, Inc. 166 p.

41731901 Thomas, E. (1990) Acifluorfen-Sodium: Determination of Dissociation Constant: Lab Project Number: 4053-90-0181-AS-001. Unpublished study prepared by Ricerca, Inc. 67 p.

41784601 Kauppila, K.; Douglass, M. (1990) Acifluorfen-Sodium: Determination of Vapor Pressure: Lab Project Number: 4053-90-0182-AS. Unpublished study prepared by Ricerca, Inc. 102 p.

41891201 Kinnaird, M. (1991) Series 61 Report for Acifluorfen Sodium TGAI and MP: Lab Project Number: 91/5090: FR9116. Unpublished study prepared by BASF Corp. 111 p

41891202 Panek, E.; Kinnard, M. (1991) Acifluorfen Sodium 5-Batch Analysis and Analysis Method

Validation: Lab Project Number: FR9118: 91052: 91/5089. Unpublished study prepared by BASF Corp. 209 p.

41891203 Kinnaird, M. (1991) Acifluorfen Sodium TGAI--Certification of Limits: Lab Project Number: FR9122: 91/5087. Unpublished study prepared by BASF Corp. 23 p.

41891204 Kinnaird, M. (1991) Determination of the Color, Physical State, Odor, Melting Point, Bulk Density and pH of Acifluorfen Sodium: Lab Project Number: F9104: FR9107. Unpublished study prepared by BASF Corp. 10 p.

41891205 Panek, E. (1991) Determination of the Acifluorfen Acid Dissociation Constant: Lab Project Number: 91046: FR9115: 91/5071. Unpublished study prepared by BASF Corp. 14 p.

41891206 Yoder, S. (1991) Determination of Acifluorfen Sodium Octanol/Water Partition Coefficient: Lab Project Number: 4104-91-0066-AS. Unpublished study prepared by Ricerca, Inc. 110 p.

41891209 Kinnaird, M. (1991) Stability of Acifluorfen Sodium TGAI when Exposed to Heat, Simulated Sunlight, and Some Metals and Metal ions: Lab Project Number: F9102: FR9117: 91/5083. Unpublished study prepared by BASF Corp. 18 p.

Case No. 2605
Chemical No. 114402

Case Name: Sodium Acifluorfen
Registrant: BASF Corporation
Product(s): TGAI of 39.6% FI (EPA Reg. No. 7969-87)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.1550	Product identity and composition	N/A ³	41891203
830.1600	Description of materials used to produce the product	Y	41891201
830.1620	Description of production process	Y	41891201
830.1670	Discussion of formation of impurities	Y	41891201
830.1700	Preliminary analysis	Y	41891202
830.1750	Certified limits	Y	41891203
830.1800	Enforcement analytical method	Y	41891202
830.6302	Color	Y	41891204
830.6303	Physical state	Y	41891204
830.6304	Odor	Y	41891204
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	41891209
830.7000	pH	Y	41891204
830.7050	UV/Visible absorption	N ⁴	
830.7200	Melting point/melting range	Y	41891204
830.7220	Boiling point/boiling range	N/A ⁵	
830.7300	Density/relative density/bulk density	Y	41891204
830.7370	Dissociation constants in water	Y	41731901, 41891205
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	41891206
830.7840	Water solubility: column elution method; shake flask method	Y	41650302
830.7950	Vapor pressure	Y	41784601

¹ Y = Yes; N = No; N/A = Not Applicable. The product chemistry data cited satisfy the requirements for the TGAI produced by Rhone-Poulenc for BASF. BASF must identify the current source of the TGAI; if the source material is not currently produced by Rhone-Poulenc, all new product chemistry data may be required.

² **Bolded** references were reviewed under CBRS No. 8172, D165551, 5/5/92, F. Toghrol; the remaining reference was reviewed under CBRS No. 8168, D165645, 9/29/92, W. Smith.

³ Data are not required for the TGAI.

⁴ The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

⁵ Data are not required because the TGAI is a solid at room temperature.

**SODIUM ACIFLUORFEN
PC Code 114402; Case 2605**

**Reregistration Eligibility Decision
Residue Chemistry Considerations**

March 29, 2000

Contract No. 68-W-99-053

**Submitted to:
U.S. Environmental Protection Agency
Arlington, VA**

**Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268**

SODIUM ACIFLUORFEN

REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

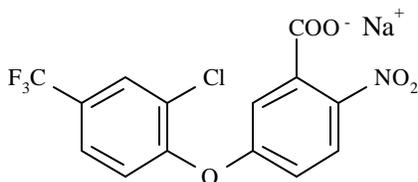
PC Code No. 114402; Case 2605

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SODIUM ACIFLUORFEN



REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code No. 114402; Case 2605

INTRODUCTION

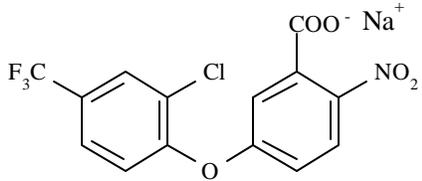
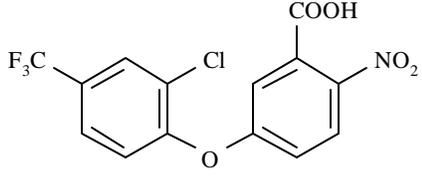
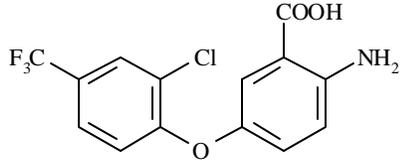
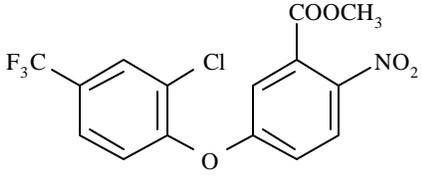
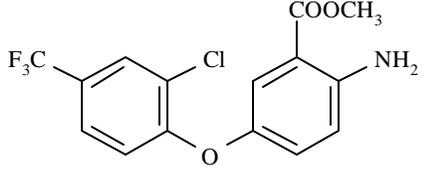
Sodium acifluorfen is a selective pre- and postemergence herbicide registered for control of annual broadleaf weeds and some grasses in rice, peanuts, and soybeans. Sodium acifluorfen end-use products are marketed in the United States under the trade names Blazer®, Galaxy®, Storm®, and Conclude® as soluble concentrate (SC) formulations. The reregistration of sodium acifluorfen is being supported by BASF, the basic producer. Sodium acifluorfen products may be applied using ground or aerial equipment.

REGULATORY BACKGROUND

The Sodium Acifluorfen Phase 4 Review dated 2/14/91 and the subsequent Sodium Acifluorfen Data-Call-In (DCI) Notice dated 6/7/91 summarized the status of available residue chemistry data for the reregistration of sodium acifluorfen. The Phase 4 Review identified several data deficiencies including plant and animal metabolism, storage stability, and magnitude of the residue in plants and animals. Several studies have been submitted and evaluated in response to the Sodium Acifluorfen DCI. This document presents an overall and up-to-date Residue Chemistry Science Assessment with respect to the reregistration of sodium acifluorfen.

The established tolerances for plant and animal commodities [40 CFR §180.383(a)] are expressed in terms of the combined residues of the herbicide sodium salt of acifluorfen [sodium 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate] and its metabolites (the corresponding acid, methyl ester, and amino analogues). Plant commodity tolerances are 0.05 ppm for strawberry and 0.1 ppm for peanuts, rice grain and straw, and soybeans; animal commodity tolerances are 0.02 ppm for milk, eggs, poultry fat, meat byproducts, and meat, and the liver and kidney of cattle, goats, hogs, horses, and sheep. Time-limited Section 18 tolerances with expiration dates of 12/31/98 are listed under 40 CFR §180.383(b) for cowpeas, lima beans, and Southern peas at 0.1 ppm. Acifluorfen is also regulated as a metabolite of the herbicide lactofen under 40 CFR §180.432. An adequate method is available for enforcement of tolerances for residues of sodium acifluorfen in/on plant and animal commodities. The chemical names and structures of sodium acifluorfen and its presently regulated metabolites are depicted in Figure A.

Figure A. Chemical Names and Structures of Sodium Acifluorfen and its Regulated Metabolites.

Compound
<p>Common Name: Sodium acifluorfen Chemical Name: Sodium 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate</p> 
<p>Common Name: Acifluorfen Chemical Name: 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoic acid</p> 
<p>Common Name: Acifluorfen amine Chemical Name: 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-aminobenzoic acid</p> 
<p>Common Name: Acifluorfen methyl ester Chemical Name: Methyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate</p> 
<p>Common Name: Acifluorfen amine methyl ester Chemical Name: Methyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-aminobenzoate</p> 

SUMMARY OF SCIENCE FINDINGS

GLN 860.1200: Directions for Use

BASF has six active sodium acifluorfen end-use products (EPs; see Table A1) registered under FIFRA Section 3 for food/feed uses [*Source: REFS search conducted 3/6/00*]. There are no active sodium acifluorfen Special Local Need (SLN) registrations under FIFRA Section 24(c).

Table A1. Sodium acifluorfen EPs with Food/Feed Uses Registered to BASF.

EPA Reg. No.	Label Acceptance Date	Formulation	Product Name
7969-76	8/5/99	1.33 lb/gal SC	Storm® Herbicide
7969-77	11/8/99	0.67 lb/gal SC	Galaxy® Herbicide
7969-79	7/7/99	2 lb/gal SC	Blazer® Herbicide
7969-80	3/14/96	2 lb/gal SC	Blazer® 2S Herbicide
7969-168	4/27/98	0.84 lb/gal SC	Conclude® Ultra Herbicide
7969-179	3/29/00	1.33 lb/gal EC	Conclude® XACT Herbicide

All product labels with use directions on rice must be modified to remove the restriction against the grazing or feeding of treated rice commodities to livestock, as the Agency believes that grazing/feeding restrictions for rice commodities are impractical. In addition, the results of the confined rotational crop study indicate that the labels for sodium acifluorfen must be amended to specify a 12-month plantback interval (PBI) for rotated crops; a 6-month PBI would be acceptable for small grain crops. If the registrant desires a shorter PBI for any other crops, limited rotational crop field trials will be required.

A comprehensive summary of sodium acifluorfen food/feed use patterns, based on the product labels registered to BASF, is presented in Table A2. A tabular summary of the residue chemistry science assessments for the reregistration of sodium acifluorfen is presented in Table B. The status of reregistration requirements for each guideline topic listed in Table B is based on the use patterns registered to BASF. For the purpose of generating this Residue Chemistry Chapter, the Agency examined the registered food/feed use patterns and reevaluated the available residue chemistry database for adequacy in supporting these use patterns.

When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels and products subject to the generic data exemption) be amended such that they are consistent with the basic producer labels.

Table A2. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Sodium Acifluorfen (Case 2605).

Site Application Timing Application Type Application Equipment ¹	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval, Days	Use Directions and Limitations ^{2,3,4}
Peanuts						
Preemergence, at cracking, or postemergence Broadcast Ground/Aerial	1.33 lb/gal SC [7969-76]	0.25 lb/A	2 (Implied)	0.5 lb/A ⁵	75	A minimum retreatment interval of 15 days is specified.
Preemergence, at cracking, or postemergence Broadcast Ground/Aerial	0.67 lb/gal SC [7969-77]	0.25 lb/A	2 (Implied)	0.42 lb/A ⁶	75	
Preemergence, at cracking, or postemergence Broadcast or banded foliar Ground/Aerial	2 lb/gal SC [7969-79] [7969-80]	0.375 lb/A	2 (Implied)	0.5 lb/A	75	A minimum retreatment interval of 15 days is specified. For banded applications, a minimum band width of 15 inches and a minimum of 15 gal/A are specified.
Rice						
Late tillering to early boot Broadcast Ground/Aerial	1.33 lb/gal SC [7969-76]	0.25 lb/A	1	0.25 lb/A	50	May be used on first and second (ratoon) crops. Rice must be past the 3-leaf stage. The following are prohibited: use of ground equipment when fields are flooded; application where commercial cultivation of catfish or crayfish is practiced; use of water containing residues from rice cultivation to irrigate crops other than soybean or peanuts.
Late tillering to early boot Broadcast or banded foliar Ground/Aerial	2 lb/gal SC [7969-79] [7969-80]	0.25 lb/A	2 (at 0.125 lb ai/A)	0.25 lb/A	50	Rice must be past the 3-leaf stage. For banded applications, a minimum band width of 15 inches and a minimum of 15 gal/A are specified. The following are prohibited: application after rice reaches the boot stage, harvesting catfish or crayfish for food from treated areas; use of water containing residues from rice cultivation to irrigate crops other than those labeled for use with this product.

Table A2 (continued).

Site Application Timing Application Type Application Equipment ¹	Formulation [EPA Reg. No.]	Maximum Single Application Rate (ai)	Maximum Number of Applications Per Season	Maximum Seasonal Rate (ai)	Preharvest Interval, Days	Use Directions and Limitations ^{2,3,4}
Soybeans						
Postemergence Broadcast foliar Ground/Aerial	1.33 lb/gal SC [7969-76] 0.67 lb/gal SC [7969-77]	0.25 lb/A	2 (Implied)	0.5 lb/A ⁵	50	A minimum retreatment interval of 15 days is specified (7969-76 only).
Postemergence Broadcast or banded foliar Ground/Aerial	2 lb/gal SC [7969-79] [7969-80]	0.375 lb/A	2 (at 0.25 lb ai/A)	0.5 lb/A	50	A minimum retreatment interval of 15 days is specified. For banded applications, a minimum band width of 15 inches and a minimum of 15 gal/A are specified.
Postemergence Broadcast foliar Ground/Aerial	0.84 lb/gal SC [7969-168]	0.25	1	0.5 lb/A ⁷	75	Soybeans must be at the second to third trifoliolate leaf stage. A 15-day minimum retreatment interval for sodium acifluorfen products is specified.

¹ Applications may be made in 10-50 gal/A by ground equipment or 5-10 gal/A by aerial equipment.

² The following are prohibited for peanuts, rice, and soybeans: cultivation within 5 days before or 7 days after application; use of treated forage or hay for feed; and grazing livestock on treated crops. A restricted entry interval (REI) of 48 hours and an 18-month plantback interval for root crops are currently in effect.

³ One of the following additives is needed depending on crop and tank mix used: ammonium sulfate, crop oil concentrate, nonionic surfactant, or urea ammonium nitrate.

⁴ Except as noted, the following components are approved for tank mixing. For peanuts: 2,4-DB, alachlor, bentazon, dimethenamid, imazamethapyr, metolachlor, paraquat, and sethoxydim. For rice: bentazon, propanil, and quinclorac. For soybeans: 2,4-D LVE (preplant burndown only), 2,4-DB, bentazon, chloransulam-methyl, chlorimuron-ethyl, clethodim, dimethenamid, fenoxaprop-p-ethyl, fluazifop-p-butyl, flumiclorac-pentyl ester, glyphosate, imazamox, imazaquin, imazethapyr, quizalofop-p-ethyl, sethoxydim, and thifensulfuron-methyl.

⁵ Including an application of the 2 lb/gal SC formulation (EPA Reg. No. 7969-79) at 0.25 lb/A following a single application of EPA Reg. Nos. 7969-76 or 7969-77 at 0.25 lb ai/A.

⁶ Including an application of the 2 lb/gal SC formulation (EPA Reg. No. 7969-79) at 0.25 lb/A following a single application of the 0.67 lb/gal SC formulation (EPA Reg. No. 7969-77) at 0.17 lb ai/A.

⁷ Including an application of other sodium acifluorfen products at 0.25 lb/A following a single application of EPA Reg. No. 7969-168 at 0.25 lb ai/A.

GLN 860.1300: Nature of the Residue - Plants

The reregistration requirements for plant metabolism are fulfilled. Acceptable metabolism studies were conducted on rice, peanuts, and soybeans for purposes of reregistration. Note that the Agency will reassess the need for additional residue characterization data in the forage if registration is sought on crops having significant livestock forage RACs. This may be necessary because, currently, metabolism study residue identification/characterization are poor on straw and hay of these crops. However, these deficiencies were not deemed critical at this time because there are restrictions against foraging/feeding peanut and soybean forage and hay.

In rice grain treated with [¹⁴C]sodium acifluorfen labeled in the chlorophenyl ring at 1.7x the maximum seasonal use rate, total radioactive residues (TRR) were 0.027 ppm in grain, 1.9-2.0 ppm in straw, and 0.16 ppm in hulls. Acifluorfen amine was the major identified metabolite in rice grain, accounting for 68% of total radioactive residues (TRR). Acifluorfen accounted for 31% TRR in rice grain, 72% TRR in rice straw, and 5-7% TRR in rice hulls. An additional metabolite, 2-chloro-4-trifluoromethylphenol, accounted for 6% TRR in rice straw.

In peanuts treated with [¹⁴C]sodium acifluorfen, labeled in the chlorophenyl ring, at 1.1x the maximum seasonal use rate, TRR were 0.18 ppm in nutmeats, 1.9 ppm in fodder, and 0.72 ppm in hulls. Acifluorfen was the major identified metabolite, accounting for 4.9% TRR in nutmeats, 11% TRR in hulls, and 13% TRR in peanut fodder. In peanut hulls two additional conjugate metabolites, 3-carboxy-4-nitrophenyl thio-beta-D-glucopyranoside and S-(3-carboxy-4-nitrophenyl)-cysteine, accounted for 26% TRR and 6.4% TRR, respectively. Numerous remaining residues in peanut matrices were characterized as being polar and present at <10% TRR.

The peanut metabolism study had previously been deemed inadequate because of insufficient characterization/identification of residues in/on peanut forage; this study can now be considered to be acceptable. No further characterization of residues in peanut forage is required because of the label restriction against feeding treated peanut hay.

In soybeans treated with [¹⁴C]-sodium acifluorfen, labeled in the nitrophenyl ring, at 1.09x the maximum seasonal use rate, TRR were 0.48 ppm in seed, 27 ppm in fodder, and 28-33 ppm in forage. Acifluorfen accounted for 8.9% TRR in seed, 58-83% TRR in forage, and 27% TRR in fodder. The conjugate metabolites identified in peanut hulls, 3-carboxy-4-nitrophenyl thio-beta-D-glucopyranoside and S-(3-carboxy-4-nitrophenyl)-cysteine, were also identified in soybean seed, accounting for 12% TRR and 6.4% TRR, respectively. In soybean forage, the only other identified metabolites were desnitro acifluorfen (0.4% TRR) and descarboxy acifluorfen (0.2% TRR). Remaining residues in soybean matrices were characterized as being multiple minor components (<10% TRR).

Tolerances for plant commodities are currently expressed in terms of the combined residues of sodium acifluorfen and its metabolites, including the corresponding acid, methyl ester, and amino analogues. The HED Metabolism Assessment Review Committee (MARC) has evaluated the available plant metabolism data and has determined that the current tolerance expression is appropriate for the purpose of reregistration (W. Hazel, 5/5/00, D265602).

GLN 860.1300: Nature of the Residue - Animals

The reregistration requirements for animal metabolism are fulfilled based on acceptable goat and poultry metabolism studies.

In goats fed [¹⁴C]sodium acifluorfen labeled in the chlorophenyl ring at a level of 10.1 ppm in the diet (– 150x the maximum theoretical dietary burden of 0.067 ppm), TRR ranged from 0.0078 ppm in milk (maximum residue observed) to 0.40 ppm in kidney (L. Cheng, 5/12/94, D192655). Acifluorfen amine was the major identified metabolite, accounting for 15% TRR in milk, 52% TRR in fat, 65% TRR in kidney, 41% TRR in liver, and 33% TRR in muscle; acifluorfen was a minor metabolite in milk and tissues, accounting for 1.0-5.2% TRR; and acifluorfen amine glucuronide accounted for – 16% TRR in milk, 6% TRR in fat, 10% TRR in kidney, 24% TRR in liver, and 19% TRR in muscle. Acifluorfen acetamide was a major metabolite in milk (– 17% TRR) but a minor metabolite in fat (4% TRR), kidney (8% TRR), liver (4% TRR), and muscle (3% TRR). Acifluorfen amino methyl ester was identified in milk (– 3% TRR), fat (5% TRR), and muscle (1% TRR). Because no ring cleavage was observed in the metabolism study, the requirement for a study with a radiolabel in the nitrophenyl ring was waived (L. Cheng, 9/16/94, D206424).

In poultry fed [¹⁴C]sodium acifluorfen labeled in either the chlorophenyl or nitrophenyl ring at 11 ppm and 9.2 ppm, respectively in the diet (– 110x and 92x the maximum theoretical dietary burden of 0.1 ppm), TRR ranged from <0.003 ppm in egg whites to 1.4 ppm in kidney. The three identified metabolites in poultry eggs and tissues were acifluorfen, acifluorfen acetamide, and descarboxy acifluorfen. Except for descarboxy acifluorfen in fat from the CPR label, which accounted for 74% TRR (0.22 ppm), residues of acifluorfen and its metabolites were present at low levels (#0.039 ppm) in poultry eggs and tissues. In poultry matrices, residues of acifluorfen ranged from 1.9% TRR in thigh muscle to 38% TRR in egg whites, residues of acifluorfen acetamide ranged from 2.1% TRR in thigh muscle to 21% TRR in egg whites, and residues of descarboxy acifluorfen ranged from 3.6% TRR in egg yolks to 74% TRR in fat.

Tolerances for animal commodities are currently expressed in terms of the combined residues of sodium acifluorfen and its metabolites, including the corresponding acid, methyl ester, and amino analogues. The MARC, on 4/4/00, evaluated the available ruminant and poultry metabolism data and determined that the current tolerance expression is not appropriate because certain additional metabolites (acifluorfen aminoglucuronide, acifluorfen acetamide, and descarboxyacifluorfen) are also expected to

have an equivalent toxicity to acifluorfen per se (W. Hazel, 5/5/00, D265602). However, upon consultation with HED's Chemistry Science Advisory Council on 5/3/00, it has been determined that 40 CFR 180.6(a)(3) is applicable, i.e., there is no reasonable expectation of residues being transferred to livestock commodities via consumption of feed items derived from crops treated with sodium acifluorfen according to the current use directions. Therefore, it is recommended that livestock tolerances be revoked.

GLN 860.1340: Residue Analytical Methods

Adequate methods are available for enforcement of tolerances of acifluorfen in plant and animal commodities as currently expressed.

Method for determination of residues in/on plant commodities: The Pesticide Analytical Manual (PAM) Volume II lists a gas chromatography/electron capture detector (GC/ECD) method, designated as Method I, for the enforcement of tolerances in plant commodities. Briefly, residues of sodium acifluorfen and acifluorfen amine are extracted with acetonitrile (ACN):1.0 N HCl (7:3, v:v). The extract is partitioned into toluene and evaporated to dryness, then dissolved in methanol, washed with heptane (oily crops only), and concentrated to dryness. The dried residue is dissolved in ethyl ether and subjected to methylation with diazomethane to convert acifluorfen and acifluorfen amine to the corresponding methyl esters, followed by derivatization with heptafluorobutyramide (HFBA) to convert the methyl ester of acifluorfen amine to the HFBA derivative. The resulting residues are purified on a Florisil column prior to GLC analysis. Method I determines residues of sodium acifluorfen, acifluorfen, acifluorfen amine, and any other compounds that can be converted to acifluorfen methyl ester or the HFBA derivative. Identifications are confirmed by GLC/MS (Method A in PAM II). The stated detection limit of Method I is 0.01-0.02 ppm. No radiovalidation data have been submitted for this method; the requirements for these data are waived based on the low residues found in metabolism and field trial studies.

BASF has submitted method validation data for the data collection method used for rice grain, straw, hulls, and bran (Method 9404/1). For determination of acifluorfen and acifluorfen methyl ester (both detected as acifluorfen methyl ester), rice raw agricultural commodities (RACs) and processed commodities are soaked in 0.1 N NaOH, then extracted with 1% acetic acid in ACN. The resulting extract is sequentially washed and re-diluted with heptane and dichloromethane (DCM) followed by 1 N HCl and acetone, then methylated with (trimethylsilyl)diazomethane. Following cleanup via silica gel solid-phase extraction, residues of acifluorfen and acifluorfen methyl ester are quantitated together as acifluorfen methyl ester by GC/ECD. For determination of acifluorfen amine and the amine methyl ester (both detected as acifluorfen amine), residues in rice samples are hydrolyzed by refluxing with 0.33 N NaOH, then extracted with concentrated acetic acid and ACN. For rice hulls and straw, potassium metabisulfite is added prior to extraction as an antioxidant. The resulting extract is diluted, and residues of acifluorfen amine and the amine methyl ester are quantitated together by HPLC with fluorescence detection. The validated limits of quantitation (LOQs) are 0.10 ppm for rice grain and bran (0.05 ppm for residues determined as acifluorfen methyl ester and 0.05 ppm for residues determined as acifluorfen amine), and >0.1 ppm for rice straw (0.05 ppm for acifluorfen and acifluorfen methyl ester and 0.05 -

0.1 ppm for acifluorfen amine and its methyl ester). If Method 9404/1 is to be proposed for tolerance enforcement purposes, a LOQ <0.1 will be required for rice straw. We note that this method was developed after the registrant observed poor recovery of aged residues from rice hulls.

BASF has conducted successful independent laboratory validation of the GC/ECD data collection method used for peanut nutmeats, peanut processed commodities (meal, crude oil, and refined oil), and soybean seed (Method D9205). This method must undergo successful Agency method validation before it is deemed acceptable as a tolerance enforcement method. In addition, the method has not been radiovalidated; adequate radiovalidation data must be submitted before the method can be considered acceptable for tolerance enforcement purposes. The registrant has stated that the method will not be used as an enforcement method, consequently, an independent laboratory validation and radiovalidation are not required at this time. Briefly, the matrix is soaked in 0.1 N NaOH for 1 hour, then extracted with 1% acetic acid in ACN. The resulting extract is diluted and analyzed by HPLC with fluorescence detection for acifluorfen amine and acifluorfen amine methyl ester. For determination of acifluorfen and acifluorfen methyl ester, extracted residues are washed with heptane and ACN. Residues in the ACN fraction are concentrated, partitioned into dichloromethane, washed with acidified water, concentrated, and methylated with (trimethylsilyl)diazomethane. Following cleanup via silica gel solid-phase extraction, residues of acifluorfen and acifluorfen methyl ester are quantitated together as acifluorfen methyl ester by GC/ECD. The validated LOQ is 0.025 ppm for each analyte. To distinguish between residues of acifluorfen and its methyl ester, analysis can be repeated without the methylation step.

Methods for determination of residues in animal commodities: Method I in PAM Volume II is also designated for the enforcement of tolerances in animal commodities. Residues of sodium acifluorfen and acifluorfen amine are extracted from milk with ACN and centrifuged; residues in tissues are extracted with ACN:water (7:3, v:v) and filtered. The resulting extracts are partitioned with HCl and toluene. Following phase separation, the organic phase is washed with water, dried over sodium sulfate, and concentrated to dryness. Tissue extracts are dissolved in methanol, washed with heptane, and concentrated to dryness. The dried residues of milk and tissues are dissolved in ethyl ether and subjected to methylation with diazomethane and analysis by GLC as described above for plants. Identifications are confirmed by GLC/MS (Method A in PAM II). The stated detection limit of Method I is 0.01-0.02 ppm. No radiovalidation data have been submitted for this method; although these data have not been submitted, they are no longer required because livestock tolerances are to be revoked. Should additional uses be added in the future that result in finite acifluorfen residues in livestock commodities, radiovalidation data and development of methods for acifluorfen aminoglucuronide, acifluorfen acetamide, and descarboxyacifluorfen will be required.

GLN 860.1360: Multiresidue Methods

The reregistration requirements for multiresidue method testing for sodium acifluorfen are satisfied. The 10/99 FDA PESTDATA database (PAM Volume I, Appendix I) indicates that acifluorfen is not recovered using Multiresidue Methods Sections 303 (Mills, Onley, and Gaither; Protocol E, nonfatty) and 304 (Mills, fatty food).

GLN 860.1380: Storage Stability Data

The reregistration requirements for storage stability data to support uses of sodium acifluorfen on peanuts, rice, and soybeans are satisfied. Storage stability data for animal commodities are not required as magnitude of the residue data in meat, milk, poultry, and eggs are not required.

Plant commodities: Storage stability data have been submitted and evaluated for rice grain and straw, peanut nutmeats, hulls, and processed fractions (meal, crude oil, and refined oil), and soybeans stored frozen (-30 to <0 C). HED previously concluded that an adequate storage stability study for peanuts would fulfill requirements for both peanuts and soybeans. The available storage stability data are adequate to validate the storage intervals and conditions of samples collected from the peanut, rice, and soybean field trials and processing studies. The Agency has concluded that the available storage stability data for rice grain are sufficient to fulfill data requirements for rice processed commodities because these fractions are obtained by simple mechanical means.

Residues of acifluorfen were stable for up to 37 months in/on rice grain, 43 months in/on rice straw, 18 months in/on peanut nutmeats, 13 months in/on peanut hulls, peanut meal, crude oil, and refined oil, and 7.5 months in/on soybeans. Residues of acifluorfen amine were stable for up to 43 months in/on rice grain and straw, 18 months in/on peanut nutmeats, 13 months in peanut meal, and 3 months in/on soybean (longest interval analyzed); residues were stable in peanut crude oil for up to 6 months, then declined by 34% at 13 months, and declined in peanut refined oil by 88% after 3 months. Residues of acifluorfen methyl ester were stable for 43 months in/on rice grain and straw, 18 months in/on peanut nutmeats, 13 months in peanut meal, crude oil, and refined oil, and 7.5 months in/on soybean; residues declined in/on peanut hulls by 35% after 6 months (longest interval analyzed). Residues of acifluorfen amine methyl ester were stable for up to 43 months in/on rice straw, 18 months in/on peanut nutmeats, 13 months in peanut meal, crude oil, and refined oil, and 7.5 months in soybeans; residues were stable in rice grain for up to 23 months and declined by -40% after 43 months.

Although the storage stability data indicate that residues of acifluorfen amine declined in peanut crude oil and peanut refined oil, and residues of acifluorfen amine methyl ester declined in peanut hulls, neither of these metabolites are expected in peanuts based on the results of the peanut metabolism study.

The storage stability data indicate that residues of acifluorfen amine methyl ester declined by 40% in rice grain after 23 months at <0 C. The current analytical methodology converts residues of acifluorfen amine to acifluorfen amine methyl ester both of which are determined as acifluorfen amine methyl ester; it also converts residues of acifluorfen to acifluorfen methyl ester both of which are determined as acifluorfen methyl ester. In the rice field trials, residues in rice grain were nondetectable (<0.05 ppm each for acifluorfen amine methyl ester and acifluorfen methyl ester). Correcting for the 40% decline on storage, residues of acifluorfen amine methyl ester would be <0.07 ppm, with combined residues amounting to <0.12 ppm, which is not significantly greater than the established tolerance of 0.1 ppm. The increase in residue levels resulting from correction for storage stability decline is not sufficiently

significant to warrant increasing the tolerance level for rice grain, especially in consideration of the fact that acifluorfen amine methyl ester was not detected in rice commodities in the rice metabolism study.

Animal commodities: The requirement for data reflecting magnitude of the residue in meat, milk, poultry, and eggs has been waived because it has been determined that animal feeding studies and tolerances are not necessary; concomitantly, the storage stability data to validate such feeding studies have also been waived. Note that storage stability data, submitted in support of the animal metabolism studies, indicate that radioactive residues of sodium acifluorfen were stable in ACN:water extracts of goat liver and in hen liver for up to 12 months of frozen storage.

GLN 860.1500: Crop Field Trials

The reregistration requirements for data depicting the magnitude of sodium acifluorfen and its metabolites in/on peanuts, rice grain and straw, and soybean seed are fulfilled.

In peanuts treated at or above the maximum registered rate of 0.5 lb ai/A (applications were made at 0.5-1.5 lb ai/A), residues of sodium acifluorfen and its regulated metabolites were below the LOQ (<0.10 ppm). We note that although PHIs in some of the peanut field trials exceeded the established PHI of 75 days (ranging up to 140 days), these data are adequate to support the registered use pattern. Following treatment according to the registered use patterns, combined residues of sodium acifluorfen and its regulated metabolites (determined as acifluorfen methyl ester and acifluorfen amine) were below the LOQ (<0.10 ppm) in/on rice grain (<0.05 ppm each, acifluorfen methyl ester and acifluorfen amine); in rice straw, combined residues ranged from <0.10 ppm to <0.124 ppm. In soybean seed, combined residues of sodium acifluorfen and its metabolites were <0.1 ppm (<0.02 ppm for each of the five regulated compounds). Data pertaining to soybean aspirated grain fractions are not required because residues in soybean seed were less than the method LOQ.

Use of sodium acifluorfen on strawberries is being supported by IR-4. There are currently no registered uses of sodium acifluorfen on strawberries.

GLN 860.1520: Processed Food/Feed

The reregistration requirements for data pertaining to magnitude of the residue in the processed commodities of rice, peanuts, and soybeans are fulfilled. The available data indicate that residues of sodium acifluorfen do not concentrate in the processed commodities of rice, peanuts, and soybeans; thus no tolerances are required.

No residues above the LOQ of 0.10 ppm (0.05 ppm each for acifluorfen methyl ester and acifluorfen amine) were found in rice grain or rice processed commodities, including polished rice, hulls, and bran, from plants treated with sodium acifluorfen at 4x the maximum registered label rate. Following treatment with sodium acifluorfen at 10x the maximum registered label rate for peanuts and soybeans,

residues were below the LOQ (<0.02 ppm each for acifluorfen, acifluorfen methyl ester, acifluorfen amine, and acifluorfen amine methyl ester) in peanut meal, crude oil, refined oil, and soapstock, and soybean meal, hulls, soapstock, crude oil, and refined oil, processed from peanut nutmeats bearing nondetectable residues and soybean seed bearing detectable residues of acifluorfen and acifluorfen methyl ester at 0.17-0.25 ppm.

GLN 860.1480: Meat, Milk, Poultry, Eggs

The reregistration requirements for data depicting magnitude of the residue in meat, milk, poultry, and eggs have been waived because, upon consultation with HED’s Chemistry Science Advisory Council on 5/3/00, it was determined that 40 CFR 180.6(a)(3) is applicable, i.e., there is no reasonable expectation of residues being transferred to livestock commodities via consumption of feed items derived from crops treated with sodium acifluorfen according to the current use directions.

Feeding studies in which cows and chickens were fed radiolabeled sodium acifluorfen were summarized in the Phase 4 Review. Though inadequate, these studies showed that at exaggerated feeding levels, total radioactivity was <0.01 ppm in meat and milk; the parent and individual metabolites were not determined. The limit of quantitation for milk, eggs, and animal tissues, except liver, was 0.01 ppm, while the limit of quantitation for liver was 0.02 ppm. Therefore, the Agency established tolerances at 0.02 ppm for the animal commodities, well above the expected secondary residue from the established tolerances in feed items. The maximum theoretical dietary burdens for ruminants and poultry are presented below.

Calculation of maximum livestock dietary burden for sodium acifluorfen.

Feed Commodity	Reassessed Tolerance (ppm)	% Dry Matter	% of Diet	Burden (ppm)
Beef and dairy cattle				
Rice, grain	0.1	88	40	0.045
Rice, straw	0.2	90	10	0.022
TOTAL			60	0.067
Poultry				
Peanuts	0.1	--	20	0.02
Rice, grain	0.1	--	60	0.06
Soybean, seed	0.1	--	20	0.02
TOTAL			100	0.1

GLN 860.1400: Water, Fish, and Irrigated Crops

Sodium acifluorfen is presently not registered for direct use on water and aquatic food and feed crops. Although sodium acifluorfen is registered for use on rice, current label restrictions prohibit the use of

water containing residues from rice cultivation to irrigate crops other than those labeled for use. Label restrictions also prohibit the harvest of catfish and crayfish for food from treated areas. Therefore, no residue chemistry data are required under these guideline topics.

GLN 860.1460: Food Handling

Sodium acifluorfen is not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

The reregistration requirements for data depicting the nature of the residue in confined rotational crops are fulfilled. The available confined rotational crop data indicate that ¹⁴C-residues >0.01 ppm accumulated in/on all rotational crop commodities of chard, turnip, sorghum, wheat, and radish planted 39, 103, 145, 313, and/or 370 days following applications of [¹⁴C]sodium acifluorfen to sandy loam soil at 1x. Acifluorfen was identified at >0.01 ppm in/on sorghum forage, fodder, and grain planted 39 days after treatment (DAT) and in/on chard and radish tops planted 103 DAT. Acifluorfen was identified at <0.001-0.003 ppm in/on wheat forage, grain, and straw planted 145 DAT, and at 0.001-0.004 ppm in/on chard and radish tops planted 313 DAT and sorghum forage, fodder, and grain planted 370 DAT.

Based on these results, the labels for sodium acifluorfen support a 12-month plantback interval (PBI) for rotated crops; a 6-month PBI would be acceptable for small grain crops. However, since the residues of concern in the confined study are greater than or equal to 0.01 ppm but less than the limit of quantitation (LOQ) of the analytical method to be used on field trial samples, HED will waive the need for limited field trials and will revise the PBI requirement to 40 days for small grains and 100 days for other crops. If the registrant desires a shorter PBI for any crop, limited field trials will then be required.

Table B. Residue Chemistry Science Assessments for Reregistration of Sodium acifluorfen.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR §180.383(a)]	Must Additional Data Be Submitted?	References ¹
860.1200: Directions for Use	Not applicable (N/A)	Yes ²	See Tables A1 and A2
860.1300: Plant Metabolism	N/A	No	41688504 , 42368301, ³ 42368302, ³ 42865801, ⁴ 42865802, ⁴ 43182001, ⁵ 43181901, ⁶ 43295501, ⁷ 43881001 ⁸
860.1300: Animal Metabolism	N/A	No	42815601, ^{9,10} 42828201 ¹¹
860.1340: Residue Analytical Methods			
- Plant commodities	N/A	No	00028858 , 42815702, ¹¹ 43451001, ¹² 44137901, ¹³ 44153801, ¹³ 92168036 , 92168048
- Animal commodities	N/A	No ¹³	00028858 , 92168036 , 92168048
860.1360: Multiresidue Methods	N/A	No	FDA PESTDATA database (PAM Vol. I, Appendix I)
860.1380: Storage Stability Data			
- Plant/processed commodities	N/A	No	00107488 , 43290101, ¹⁴ 43601401, ¹⁵ 43666602, ¹³ 44137901, ¹³ 92168037 , 92168049
- Animal commodities	N/A	No ¹⁶	42815601 ⁹ , 42828201 ¹¹
860.1500: Crop Field Trials			
<u>Legume Vegetables (Succulent or Dried) Group</u>			
- Soybean, seed and aspirated grain fractions	0.1, seed	No ¹⁷	00107488 , 42815701, ¹¹ 92168045 , 92168053
<u>Foliage of Legume Vegetables Group</u>			
- Soybean, forage and hay	None established	No ¹⁸	

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR §180.383(a)]	Must Additional Data Be Submitted?	References ¹
<u>Cereal Grains Group</u>			
- Rice, grain	0.1	No	42330604, ¹⁹ 43584502 ²⁰
<u>Fodder, Forage, Hay, and Straw of Cereal Grains Group</u>			
- Rice, straw	0.1	No	42330604, ²⁰ 43584502 ²¹
<u>Miscellaneous Commodities</u>			
- Peanut	0.1	No	00028857, 00028858, 92168042, 92168052
- Strawberry	0.05	No ²¹	PP#0E3821, ²² 41285901 ²³
860.1520: Processed Food/Feed			
- Peanut	None established	No	43254901 ²⁴
- Rice	None established	No	42330605, ²⁰ 43584501 ²¹
- Soybean	None established	No	43254902 ²⁵
860.1480: Meat, Milk, Poultry, Eggs			
- Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	0.02, milk, kidney, liver	No ²⁵	00107488, 92168050
- Eggs and the Fat, Meat, and Meat Byproducts of Poultry	0.02, eggs, fat, mbyp, and meat	No ²⁶	00107488, 92168050
860.1400: Water, Fish, and Irrigated Crops			
860.1460: Food Handling			
860.1850: Confined Rotational Crops			
860.1900: Field Rotational Crops			

1. **Bolded** references were evaluated in the Sodium Acifluorfen Phase 4 Review (S. Funk, 2/14/91). All other references were reviewed as noted.

Table B (*continued*).

2. All product labels with use directions on rice must be modified to remove the restriction against the grazing or feeding of treated rice commodities.

Based on the results of the confined rotational crop study, the labels for sodium acifluorfen must be amended to specify an 100 day plantback interval (PBI) for rotated crops; a 40 day PBI would be acceptable for small grain crops.

3. DP Barcode D180455, 12/8/92, J. Abbotts.
4. DP Barcode D194099, 11/2/93, J. Abbotts.
5. DP Barcode D201623, 5/4/94, F. Suhre.
6. DP Barcode D201621, 5/5/00, W. Hazel.
7. DP Barcode D205291, 6/8/95, S. Knizner.
8. DP Barcode D222843, 4/4/96, L. Cheng.
9. DP Barcode D192655, 5/12/94, L. Cheng.
10. DP Barcode D206424, 9/16/94, L. Cheng.
11. DP Barcode D192899, 4/26/94, L. Cheng.
12. DP Barcodes D209767, D213458, and D216267, 5/5/00, W. Hazel.
13. As livestock tolerances are to be revoked, no additional data regarding analytical methods for livestock commodities are required.
14. DP Barcode D205090, 8/15/94, S. Knizner.
15. DP Barcode D214314, 6/5/95, S. Knizner.
16. Data requirements pertaining to storage stability of acifluorfen residues in animal commodities are no longer required as it has been determined that data reflecting magnitude of the residue in meat, milk, poultry, and eggs are not required.
17. Data pertaining to soybean aspirated grain fractions are not required because residues in soybean seed were less than the method LOQ.
18. Data are not required because of the label restrictions against feeding or grazing treated forage or hay.
19. DP Barcode D179054, 12/4/92, S. Knizner.
20. DP Barcode D213553, 6/14/95, S. Knizner.
21. Use on strawberries is being supported by IR-4; currently there are no registered uses of sodium acifluorfen on strawberries. Before registration may be granted, the Agency must assure that the field trial database reflects the proposed labels
22. CB No. 7082, 3/4/91, S. Bacchus.

Table B (*continued*).

23. CB No. 6029, 6/8/90, S. Inasi.
24. DP Barcode D204306, 6/5/95, S. Knizner.
25. The reregistration requirements for data depicting magnitude of the residue in meat, milk, poultry, and eggs have been waived because the available ruminant and poultry metabolism studies and usage information indicate that residues are not expected to transfer to livestock from treated feed items.
26. DP Barcode D192150, 5/12/94, L. Cheng.
27. DP Barcode D207702, 9/29/94, R. Perfetti.
28. Based on the results of the confined rotational crop studies, the labels for sodium acifluorfen support a 12-month plantback interval (PBI) for rotated crops; a 6-month PBI would be acceptable for small grain crops. However, since the residues of concern in the confined study are greater than or equal to 0.01 ppm but less than the limit of quantitation (LOQ) of the analytical method to be used on field trial samples, HED will waive the need for limited field trials and will revise the PBI requirement to 40 days for small grains and 100 days for other crops. If the registrant desires a shorter PBI for any crop, limited field trials will then be required.

TOLERANCE REASSESSMENT SUMMARY

Tolerances for residues in/on plant and animal commodities are established under 40 CFR §180.383. They are currently expressed in terms of the combined residues of the herbicide sodium salt of acifluorfen [sodium 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoic acid] and its metabolites (the corresponding acid, methyl ester, and amino analogues). The qualitative nature of the residue in plants and animals is adequately understood. HED has determined that the current tolerance expression for plant commodities is appropriate. As there is no reasonable expectation that residues will transfer from treated feed items to livestock tissues, HED recommends that livestock tolerances be revoked.

The chemical name for sodium acifluorfen listed in 40 CFR needs to be corrected; the correct name is "sodium 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate." In addition, at the time that the chemical name is corrected, the tolerance expression should be revised to specifically define the regulated metabolites.

A summary of sodium acifluorfen tolerance reassessments is presented in Table C.

Tolerances Established Under 40 CFR §180.383(a)

Sufficient field trial data reflecting the maximum label use pattern are available to reassess the established tolerances for the following RACs **as defined**: peanuts; rice grain and rice straw; and soybeans. The established tolerances listed under 40 CFR §180.383(a) are reassessed at the same levels except those listed for rice straw. Higher tolerances are required for rice straw to reflect the results of recent field trials.

Revocation of the established tolerances for acifluorfen in livestock commodities is recommended as there is no reasonable expectation that residues will transfer from treated feed items to livestock commodities.

Time-Limited Tolerances Established Under 40 CFR §180.383(b)

Time-limited tolerances to support Section 18 emergency exemptions were established for the following RACs **as defined**: cowpeas, lima beans, and Southern peas. The listed expiration date for these tolerances was 12/31/98. On April 19, 1999, EPA denied the use of sodium acifluorfen on cow peas, lima beans, and Southern peas and stated that the tolerances could not be extended because EPA was unable to make the safety finding required under FQPA (65 FR 3699, 1/24/2000).

Pending Tolerance PetitionsPP#1F3953: BASF has proposed the establishment of tolerances for residues of sodium acifluorfen and its metabolites in/on dry beans and sunflowers at 0.05 ppm. The petition is currently in reject status pending resolution of deficiencies pertaining to residue analytical

methods, storage stability data, and the submission of additional crop field trial data (DP Barcode D210659, 5/30/95, W. Cutchin).

Table C. Tolerance Reassessment Summary for Sodium Acifluorfen.

Commodity	Current Tolerance, ppm	Reassessed Tolerance, ppm	Comment <i>[Correct Commodity Definition]</i>
Tolerances Established Under 40 CFR §180.383(a)			
Cattle, kidney	0.02	Revoke ¹	
Cattle, liver	0.02	Revoke	
Eggs	0.02	Revoke	<i>[Egg]</i>
Goats, kidney	0.02	Revoke	<i>[Goat, kidney]</i>
Goats, liver	0.02	Revoke	<i>[Goat, liver]</i>
Hogs, kidney	0.02	Revoke	<i>[Hog, kidney]</i>
Hogs, liver	0.02	Revoke	<i>[Hog, liver]</i>
Horses, kidney	0.02	Revoke	<i>[Horse, kidney]</i>
Horses, liver	0.02	Revoke	<i>[Horse, liver]</i>
Milk	0.02	Revoke	
Peanuts	0.1	0.1	<i>[Peanut]</i>
Poultry, fat	0.02	Revoke	
Poultry, mbyp	0.02	Revoke	
Poultry, meat	0.02	Revoke	
Rice grain	0.1	0.1	<i>[Rice, grain]</i>
Rice straw	0.1	0.2	The available data, reflecting the maximum registered use pattern, indicate that the maximum combined residues of sodium acifluorfen and metabolites were <0.124 ppm in/on rice straw. <i>[Rice, straw]</i>
Sheep, kidney	0.02	Revoke	
Sheep, liver	0.02	Revoke	
Soybeans	0.1	0.1	<i>[Soybean, seed]</i>
Strawberry	0.05	[0.05]	Use of sodium acifluorfen on strawberries is being supported by IR-4. Currently there are no registered uses of sodium acifluorfen on strawberries. Tolerance reassessment cannot be finalized until there are approved use directions.
Tolerances Established Under 40 CFR §180.383(b)			
Cowpeas	0.1	Revoke	Expiration date 12/31/98.
Lima beans	0.1	Revoke	Extension of the expiration date for these tolerances has been denied (65 FR 3699, 1/24/2000)
Southern peas	0.1	Revoke	

- ¹ Tolerances for residues of acifluorfen in livestock commodities should be revoked because it has been determined that there is no reasonable expectation that residues will transfer from treated feed items to livestock commodities.

CODEX HARMONIZATION

There are no Codex MRLs for sodium acifluorfen; therefore, there are no issues with respect to compatibility of Codex MRLs and U.S. tolerances.

AGENCY MEMORANDA RELEVANT TO REREGISTRATION

CB No.: 6029
Subject: PP#0E3821, (EPA Reg. No. 7969-79): Acifluorfen (Blazer®) In or On Strawberry. Evaluation of Analytical Method and Residue Data.
From: S. Inasi
To: A. Beard
Dated: 6/8/90
MRID: 41285901

CB No.: 7082
Subject: PP#0E3821, (EPA Reg. No. 7969-79): Acifluorfen (Blazer®) In or On Strawberry. Amendment Letter dated 9/10/90: Revised Section F; Confirmation of Formulation.
From: S. Bacchus
To: H. Jamerson
Dated: 3/4/91
MRID: None

DP Barcode: D169747
Subject: Reregistration of Sodium Acifluorfen. BASF Corp. 90 Day Response to Phase 4 DCI.
From: S. Funk
To: T. Luminello
Dated: 12/5/91
MRID: None

DP Barcode: D168104
Subject: Sodium Acifluorfen. List B Case No. 2605. BASF Corporation Response to Phase 4 Review of the Magnitude of the Residue in Meat/Milk/Poultry/Eggs.
From: F. Fort
To: T. Luminello/L. Deluise
Dated: 1/22/92
MRID: None

DP Barcode: D172647
Subject: Acifluorfen. Anticipated Residues on Soybeans and Milk.
From: M. Bradley
To: H. Jamerson and Toxicology Branch
Dated: 2/5/92
MRID: None

DP Barcode: D177393
Subject: Sodium Acifluorfen. Soybeans. Blazer Herbicide (EPA Reg. No. 7969-79)
Label Revision Reducing Use Rate and Impact on DCI dated 6/7/91. Case #
2605. Chemical # 114402.
From: J. Smith
To: T. Luminello
Dated: 6/9/92
MRID: None

DP Barcode: D179054
Subject: Sodium Acifluorfen. Reregistration Case No. 2605. Guideline 171-4(k) and 171-
4(l) Magnitude of the Residue Studies for Rice and Rice Grain Processing.
From: S. Knizner
To: T. Luminello
Dated: 12/4/92
MRID: 42330604 and 42330605

DP Barcode: D178405
Subject: Sodium Acifluorfen, Determination of Anticipated Residues.
From: J. Abbotts
To: H. Jamerson
Dated: 12/4/92
MRID: None

DP Barcode: D180455
Subject: Sodium Acifluorfen, Reregistration. BASF Corporation Response to Phase 4
Review. Metabolism in Peanuts and Rice.
From: J. Abbotts
To: J. Ellenberger
Dated: 12/8/92
MRID: 42368301 and 42368302
DP Barcode: D194099
Subject: Sodium Acifluorfen, Reregistration. Nature of the Residue in Peanut and Rice.

From: J. Abbotts
To: J. Ellenberger
Dated: 11/2/93
MRID: 42865801 and 42865802

DP Barcode: D192899
Subject: Sodium Acifluorfen. Case No. 2605. Nature of Residue in Poultry, Residue Method in Plants, and Magnitude of Residue in Soybeans.

From: L. Cheng
To: K. Davis/T. Luminello
Dated: 4/26/94
MRID: 42815701, 42815702, and 42828201

DP Barcode: D201623
Subject: Sodium Acifluorfen (114402). Nature of the Residue in Rice 171-4(a); Supplemental Data to Upgrade Rice Metabolism Study.

From: F. Suhre
To: J. Ellenberger
Dated: 5/4/94
MRID: 43182001

DP Barcode: D192150
Subject: Sodium Acifluorfen. Case No. 2605. Confined Rotational Crop Study in Chard, Radish, Turnips, Sorghum, and Wheat.

From: L. Cheng
To: T. Luminello
Dated: 5/12/94
MRID: 42785601

DP Barcode: D192655
Subject: Sodium Acifluorfen. Case No. 2605. Nature of the Residue in Goats.
From: L. Cheng
To: T. Luminello
Dated: 5/12/94
MRID: 42815601

DP Barcode: None
Subject: Sodium Acifluorfen. Reregistration Case No. 2605. Chemical No. 114402.
From: S. Knizner
To: Files

Dated: 5/26/94
MRID: None

DP Barcode: D204442
Subject: Sodium Acifluorfen. Request for Time Extension. Reregistration Case No. 2605. Chemical No. 114402.
From: S. Knizner
To: T. Luminello
Dated: 7/5/94
MRID: None

DP Barcode: D205090
Subject: Sodium Acifluorfen. Peanut Storage Stability Study Progress Report. Reregistration Case No. 2605. Chemical No. 114402.
From: S. Knizner
To: T. Luminello
Dated: 8/15/94
MRID: 43290101

DP Barcode: D197871
Subject: Sodium Acifluorfen: Determination of Anticipated Residues.
From: J. Garbus
To: H. Jamerson
Dated: 8/29/94
MRID: None

DP Barcode: D206424
Subject: Sodium Acifluorfen. Case No. 2605. Ruminant Metabolism Study with Carbon-14 Labeled in the Nitrophenyl Ring - Waiver Request.
From: L. Cheng
To: T. Luminello
Dated: 9/16/94
MRID: None

DP Barcode: D207702
Subject: Response to the Sodium Acifluorfen DCI: Confined Rotational Crop Study and Time Extension Request (Case 2605, Chemical I.D. No. 114402).
From: R. Perfetti
To: E. Saito
Dated: 9/29/94

MRID: 43372501

DP Barcode: D210659
Subject: PP#1F3953, Response to Review. Sodium Acifluorfen on Dry Beans and Sunflowers. Chemical # 114402.
From: W. Cutchin
To: J. Miller
Dated: 5/30/95
MRID: None

DP Barcode: D214314
Subject: Sodium Acifluorfen. Rice Storage Stability Study Progress Report. Reregistration Case No. 2605. Chemical No. 114402.
From: S. Knizner
To: T. Luminello
Dated: 6/5/95
MRID: 43601401

DP Barcode: D204306
Subject: Sodium Acifluorfen. Peanut and Soybean Processing Study. Reregistration Case No. 2605. Chemical No. 114402.
From: S. Knizner
To: T. Luminello
Dated: 6/5/95
MRID: 43254901 and 43254902

DP Barcode: D205291
Subject: Sodium Acifluorfen. Nature of the Residue in Peanuts. Reregistration Case No. 2605. Chemical No. 114402.
From: S. Knizner
To: T. Luminello
Dated: 6/8/95
MRID: 43295501

DP Barcode: D213553
Subject: Sodium Acifluorfen. Magnitude of the Residue in Rice and Rice Processed Commodities. Reregistration Case No. 2605. Chemical No. 114402.
From: S. Knizner
To: T. Luminello
Dated: 6/14/95

MRID: 43584501 and 43584502

DP Barcode: D222843
Subject: Sodium Acifluorfen. Case 2605. Repeat Characterization of Residues in Rice Straw.
From: L. Cheng
To: T. Luminello
Dated: 4/4/96
MRID: 43881001

DP Barcode: D201621
Subject: Evaluation of soybean metabolism data in support of reregistration of sodium acifluorfen.
From: W. Hazel
To: C. Scheltema
Dated: 5/5/00
MRID: 43181901

DP Barcode: D209767, D213458, and D216267
Subject: Evaluation of residue analytical method, storage stability, and supplemental confined rotational commodity data in support of reregistration of sodium acifluorfen.
From: W. Hazel
To: C. Scheltema
Dated: 5/5/00
MRID: 43451001, 43666601, 43666602, 44137901, and 44153801

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